Genetic Testing

Policy Number: BIP072.M
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Instructions for Use

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Related Benefit Interpretation Policy

- Maternity and Newborn Care

Related Medical Management Guidelines

- Genetic Testing for Hereditary Cancer
- Preimplantation Genetic Testing and Related Services
- Preventive Care Services

Federal/State Mandated Regulations

Oklahoma

Oklahoma Statute Title 36 Section 6060.5a (Effective January 1, 2024)

Section 6060.5a - [Effective 1/1/2024], Okla. Stat. tit. 36 § 6060.5a | Casetext Search + Citator

A. As used in this section:
   1. "Biomarker" means a biological molecule found in blood, other body fluids, or tissues that is a sign of a normal or abnormal process, or of a condition or disease. A biomarker may be used to see how well the body responds to a treatment for a disease or condition or for other purposes. Biomarkers shall include but are not limited to gene mutation or protein expression;
   2. "Biomarker testing" means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing shall include but not be limited to single-analyte tests, multiplex panel tests, gene or protein expression, and whole exome, whole genome, and whole transcriptome sequencing;
   3. "Clinical utility" means the test result provides information that is used in the formulation of a treatment or monitoring strategy that informs a patient's outcome and impacts the clinical decision. The most appropriate test may include both information that is actionable and some information that cannot be immediately used in the formulation of a clinical decision;
   4. "Consensus statement" means a statement that:
      a. Is developed by an independent, multidisciplinary panel of experts that use a transparent methodology and reporting structure that includes a conflict of interest policy,
      b. Is based on the best available evidence for the purpose of optimizing clinical care outcomes, and
      c. Is aimed at specific clinical circumstances;
   5. "Health benefit plan" means a plan as defined pursuant to Section 6060.4 of Title 36 of the Oklahoma Statutes; and
   6. "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines that:
      a. Are developed by independent organizations or medical professional societies using a transparent methodology and reporting structure and a conflict of interest policy, and
      b. Establish standards of care that are informed by a systemic review of evidence and an assessment of the benefits and costs of alternative care options that includes recommendations intended to optimize patient care.

B. Any health benefit plan, including the Oklahoma Employees Insurance Plan, that is offered, issued, or renewed in this state on or after the effective date of this act shall provide coverage for biomarker testing. A contract provided with a health benefit plan under this section shall include biomarker testing for the purpose of diagnosis, treatment, appropriate

management, or ongoing monitoring of an insured's disease or condition to guide treatment decisions when the biomarker test provides clinical utility as demonstrated by medical and scientific evidence including, but not limited to:
1. Labeled indications for tests that are approved or cleared by the United States Food and Drug Administration;
2. Indicated tests for a drug that is approved by the United States Food and Drug Administration;
3. Warnings and precautions on United States Food and Drug Administration-approved drug labels;
4. Centers for Medicare and Medicaid Services national coverage determinations or Medicare administrative contractor local coverage determinations; or
5. Nationally recognized clinical practice guidelines and consensus statements.

C. A health benefit plan shall ensure that coverage is provided in a manner that limits disruptions in care, including the need for multiple biopsies and biospecimen samples.

D. An insured and a prescribing practitioner shall have access to a clear, readily available, and convenient process to request an exception to a coverage policy of a health benefit plan under this subsection. The process shall be readily accessible on the plan's website. This subsection shall not be construed to require a separate process if the health benefit plan's existing process complies with this subsection.

Oregon

Oregon House Bill 3391 Reproductive Health Equity Act: Report to the Legislature (oregon.gov)
HB3391 (oregonlegislature.gov)
Screening to determine whether counseling related to the BRCA1 or BRCA2 genetic mutations is indicated, and counseling related to the BRCA1 or BRCA2 genetic mutations if indicated.

Washington

WAC Section 246-680-010 Definitions (Effective July 1, 2022)

http://app.leg.wa.gov/WAC/default.aspx?cite=246-680-010&pdf=true
The definitions in this section apply throughout this chapter unless the context clearly requires otherwise:

(1) "Amniocentesis" means a procedure to remove a small amount of amniotic fluid from the uterus of a pregnant person in order to perform one or more of the following laboratory tests:
   (a) Measure the level of alpha-fetoprotein;
   (b) Measure the level of acetylcholinesterase;
   (c) Cytogenetic studies on fetal cells including chromosome analysis, cytogenomic microarray analysis (CMA), and fluorescent in-situ hybridization (FISH);
   (d) Biochemical studies on fetal cells or amniotic fluid;
   (e) Deoxyribonucleic acid (DNA) studies on fetal cells for single gene disorders or fetal genotyping for isoimmunization studies; and
   (f) Infectious disease studies.

(2) "Carrier screening" means a procedure to remove blood or other tissue from one or both parents in order to perform laboratory analysis to establish chromosome constitution or recessive or X-linked genetic carrier status of the parents.

(3) "Chorionic villus sampling" means a procedure to remove a small number of cells from the developing placenta, in order to perform one or more of the following laboratory tests:
   (a) Cytogenetic studies on fetal cells including chromosome analysis, cytogenomic microarray analysis (CMA), and fluorescent in-situ hybridization (FISH);
   (b) Biochemical studies on placental cells; and
   (c) DNA studies on placental cells for single gene disorders.

(4) "Hepatitis B surface antigen (HBsAg) screening" means a procedure involving obtaining blood from a pregnant person to test for maternal hepatitis B infection.

(5) "Maternal serum marker screening" means a procedure involving obtaining blood from a pregnant person in order to measure through laboratory tests the level of certain products that are associated with increased risks to the fetus or pregnancy such as alpha-fetoprotein, unconjugated estriol, human gonadotropin, inhibin, or PAPP-A.

(6) "Percutaneous umbilical blood sampling" means a procedure to obtain blood from the fetus, in order to perform one or more of the following laboratory tests:
   (a) Cytogenetic studies on fetal cells including chromosome analysis, cytogenomic microarray analysis (CMA), and fluorescent in-situ hybridization (FISH);
   (b) Viral titer studies;
   (c) Fetal blood typing for isoimmunization studies;

(d) Prenatal diagnostic tests for hematological disorders;
(e) DNA studies on fetal cells for single gene disorders; and
(f) Biochemical studies on fetal blood.

(7) "Postprocedure genetic counseling" means individual counseling that may be part of another procedure, or service involving a health care provider and a pregnant person with or without other family members, to discuss the results of the prenatal tests done, any further testing or procedures available or referrals for further consultation or counseling.

(8) "Prenatal cell free DNA screening," sometimes called noninvasive prenatal screening, means drawing blood from the pregnant person to perform laboratory analysis on the cell free DNA circulating in the maternal blood stream.

(9) "Prenatal test" means any test or procedure to screen for or diagnose congenital or heritable disorders of a fetus.

(10) "Prenatal ultrasonography" means a procedure resulting in visualization of the uterus, the placenta, the fetus, and internal structures through use of sound waves.

(11) "Preprocedure genetic counseling" means individual counseling that may be part of another procedure, or service, involving a health care provider and a pregnant person with or without other family members, to assess and identify increased risks for congenital abnormalities or pregnancy complications, offer specific carrier screening or diagnostic tests, discuss the purposes, risks, accuracy, and limitations of a prenatal testing procedure, aid in decision making and to assist, when necessary, in obtaining the desired testing or procedure.

State Market Plan Enhancements

None

Covered Benefits

Important Note: Covered benefits are listed in *Federal/State Mandated Regulations*, *State Market Plan Enhancements*, and *Covered Benefits* sections. Always refer to the *Federal/State Mandated Regulations* and *State Market Plan Enhancements* sections for additional covered services/benefits not listed in this section.

Refer to the member's Evidence of Coverage (EOC) and Schedule of Benefits (SOB)

Genetic testing and counseling when determined by UnitedHealthcare's medical director or designee to be medically necessary.

Not Covered

- Members who do not meet UnitedHealthcare's medical necessity criteria for genetic testing and counseling.
- Genetic testing for the sole purpose of determining the gender of a fetus.
- Genetic testing when member has no clinical evidence or medical indication, (i.e., high risk status or strong family history) of a genetic abnormality.
- Genetic testing for non-UnitedHealthcare members.
- Genetic testing and counseling to screen newborns, children or adolescents to determine carrier status for inheritable disorders when there would be no immediate medical benefit or when the test results would not be used to initiate medical interventions during childhood.
- Genetic testing and counseling for non-medical reasons (e.g., court ordered tests, work related tests, paternity tests).

Policy History/Revision Information

Date	State(s) Affected	Summary of Changes
04/01/2024	All	**Not Covered** • Revised list of non-covered services; removed "non-medically necessary genetic testing and counseling" **Supporting Information** • Archived previous policy version BIP072.L

Date	State(s) Affected	Summary of Changes
	Oregon	**Federal/State Mandated Regulations** • Updated reference link to *Oregon House Bill 3391*

Instructions for Use

Covered benefits are listed in three (3) sections: *Federal/State Mandated Regulations*, *State Market Plan Enhancements*, and *Covered Benefits*. All services must be medically necessary. Each benefit plan contains its own specific provisions for coverage, limitations, and exclusions as stated in the member's Evidence of Coverage (EOC)/Schedule of Benefits (SOB). If there is a discrepancy between this policy and the member's EOC/SOB, the member's EOC/SOB provision will govern.